

510(k) Summary

1. Device Name:

Trade Name: PVS 1300 Neuro Guidewire
Common Name: Guidewire
Classification Name: Catheter guide wire

2. Establishment Name and Registration Number:

Name: Precision Vascular Systems, Inc.
Number: 1724618

3. Classification:

WIRE, GUIDE, CATHETER 74DQX II 870.1330

§870.1330 Catheter guide wire. (a) Identification. A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel. (b) Classification. Class II

Device Classification: Class II
Classification Panel: Previous guide wire was Cardiovascular
Product Code: 74DQX was for previous Cardio guide wire

4. Special Controls:

Not applicable to this device.

5. Labeling:

IMPORTANT: Draft labeling is attached in appendix I.

Warnings and Cautions:	Please see Appendix I.
Known contraindications to date:	Please see Appendix I.
Side-effects and complications:	Please see Appendix I.
Pre-operatively:	Please see Appendix I.
Intra-operatively:	Please see Appendix I.
Post-operatively:	Please see Appendix I.

6. Class III Certification:

Class III certification is not applicable to this device

7. Photographs:

Please see Appendix II for graphics of device.

8. Drawings:

Please see Appendix II for drawings of the device.

9. Equivalent/Predicate Devices:

Target Therapeutics FasDasher®-14 (K950069)
Target Therapeutics/ Medi-Tech Transend™ EX (K964611, K934122)
Target Therapeutics Taper®-14 Flex Tip (K924987)

10. Device Description:

The PVS 1300 neuro guide wire is a 0.014" outside diameter, single-use guidewire, which is used to gain intravascular access to and to facilitate the positioning and exchange of catheters in small diameter, tortuous vasculature for neuro-interventional procedures. The wire can be torqued to facilitate navigation through the vasculature. Refer also to the description in Appendix VI.

Materials: The proximal wire material is stainless steel. The tip material of the guidewire is nitinol. The marker coil is platinum wire. The guidewire is coated to provide lubricity. Refer also to the material description in Appendix II.

Instrumentation: There is no instrumentation applicable to this device.

11. Modified Device Data:

This section is not applicable to this device.

12. Applicants Name and Address:

Precision Vascular Systems, Inc.
2405 West Orton Circle
West Valley City, Utah 84119
801-974-1700 Telephone
801-974-1740 Fax

13. Company & Submission Contact:

John R. Ragazzo
Precision Vascular Systems, Inc.
2405 West Orton Circle
West Valley City, Utah 84119
801-974-1704 Telephone
801-974-1740 Fax

14. Manufacturing Facility:

The device will be manufactured at the company facility at 2405 West Orton Circle, West Valley City, Utah 84119.

15. Comparison Table:

Please refer to Appendix IV, Rationale for Substantial Equivalence

16. Voluntary Standards:

US Food and Drug Administration-mandated performance standards for this device do not exist. This device and its method of manufacture comply with applicable harmonized standards and the Quality System Regulation (21CFR Part 820) and ISO 9001/EN 46001 Medical Device Directive 93/42/EEC requirements.

17. Performance Data:

The PVS 1300 neuro guidewire performance was compared to predicate devices by testing tensile strength, torque strength, torqueability, tip flexibility, coating adherence / Integrity, catheter compatibility, guidewire fatigue testing, and shelf life testing. Please refer to appendix III for reports of the testing performed on the PVS 1300 neuro guidewire.

Tensile Strength – The PVS 1300 neuro guidewire had similar values of tensile strength compared to three predicate devices, similar to two predicate devices and lower tensile strength than one predicate device.

Torque Strength – The PVS 1300 neuro guidewire had approximately 3 times higher torsional stiffness than two predicate devices, and approximately 1.5 times higher torsional stiffness than the other predicate device. The PVS 1300 neuro guidewire transmits greater torque than the predicate devices.

Torqueability – The PVS 1300 neuro guidewire had better torqueability (i.e., less difference between proximal input angle and distal tip output angle in a simulated tortuous anatomy) than the predicate devices.

Tip Flexibility – The PVS 1300 neuro guidewire had similar values of tip flexibility compared to three predicate devices. The PVS wire was slightly more flexible than all three predicates.

Coating Adherence / Integrity - The PVS 1300 neuro guidewire had coating adhesion/flake resistance that was similar to that of the Transend guidewire to which it was compared.

Catheter Compatibility – The PVS 1300 neuro guidewire had catheter compatibility that was similar to that of the three predicate devices. It is compatible with the leading neuro micro-catheters including the Target Renegade 18, FasTracker-18, Cordis Rapid Transit 18, Cordis Prowler 14, and the Tracker Excel 14.

Guidewire Fatigue – The PVS 1300 neuro guidewire was fatigue tested in a simulated neuro-vascular model. The wires did not significantly degrade after twenty cycles of insertion and withdrawal from the model.

Shelf life testing was completed for PVS 1300 neuro guidewires that were accelerated aged for an equivalent of 7 months. This testing determined that the product is suitable for use for 7 months.

The results of the performance testing establish that the PVS 1300 neuro guidewire is substantially equivalent in physical performance characteristics to its predicate devices and is safe and effective.

Biocompatibility Data: The PVS 1300 neuro guidewire biocompatibility was tested per FDA guidance for an external communicating device in contact with circulating blood for less than 24 hours. Tests performed include cytotoxicity, systemic toxicity, intracutaneous reactivity, sensitization, and hemocompatibility. The PVS 1300 neuro guidewires passed all biocompatibility testing. Please refer to appendix III for results of the performed testing.

Limulus Amebocyte Lysate- LAL testing was performed and the detected endotoxin is less than the maximum allowable endotoxin level of ≤ 20 EU/device. See Appendix III for details.

18. Storage, Packaging and Sterilization Information:

Storage and Handling: Store in a cool, dark, dry place.

Packaging: Inspect all packaging upon receipt for evidence of damage. Do not use open or damaged packages. The expiration date for sterilization must be checked prior to use. Only those products that are used prior to the shelf life expiration date may be considered sterile. Every precaution should be taken to ensure sterility when opening the device's packaging. Damaged packaging may render the product unsafe for use.

Sterilization: The guide wires are supplied pre-sterilized by gamma radiation. The selected radiation dose is 25 kGy or greater. The Sterility Assurance Level (SAL) is 10^{-6} or greater. The device is not intended to be cleaned or re-sterilized by the user. The product will be sterilized per the requirements of ISO 11137.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John R. Ragazzo
Vice President of RA/QA
Precision Vascular Systems, Inc.
2405 West Orton Circle
West Valley City, UT 84119

Re: K002907
Trade Name: PVS 1300 Neuro Guidewire
Regulatory Class: II (two)
Product Code: DQX
Dated: January 10, 2001
Received: January 11, 2001

Dear Mr. Ragazzo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. John R. Ragazzo

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



for

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Precision Vascular Systems, Inc.

PVS 1300 Neuro Guide Wire
Indications for Use

Page 1 of 1

510(k) Number (if known): K002907

Device Name: **PVS 1300 Neuro Guide Wire**

Indications for Use:

1. These guidewires are intended for use in neuro-intravascular use to introduce and position catheters and other interventional devices within the neuro-vasculature.
- 2.
- 3.
- 4.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)


Prescription Use ☒

OR

Over-the-Counter Use ☐

(Per 21 CFR 801.109)

(Optional Format 1-2-96)


Division of Cardiovascular & Respiratory Devices
510(k) Number K002907